

REMARKS

In the aforesaid Office Action, the amendment filed 10/13/2006 was objected to under 35 USC 132(a) as introducing new matter, claims 26, 28-29, were rejected under 35 USC 102(b) as being anticipated by Wang et al. (US 5,556,383), and claims 30-33, 36 and 37 were rejected under 35 USC 103(a) as being unpatentable over Wang et al. alone. Claims 26 and 28-37 are pending (and Applicants note that the Examiner has not included claims 34 and 35 in the art rejections in the aforesaid Office Action).

The Examiner objected to the amendment of 10/13/2006 under 35 USC 132(a), stating that the added material which is not supported by the original disclosure is as follows: in claim [26]: “a blow-molded inflated volume”, and “an inflation pressure required to fill the blow-molded inflated volume”.

Applicants have amended claim 26 to set forth that the radial shrinkage of the balloon (the balloon being a blow-molded balloon having an inflated configuration with a shape corresponding to an inner surface of a balloon mold) is measured by a percent change between the inflated configuration outer diameter at the inflation pressure at a substantially ambient temperature in the balloon mold used to blow-mold the balloon and the inflated configuration outer diameter at the inflation pressure at the substantially ambient temperature as part of a catheter system after exposure to a shrinking treatment which causes the radial shrinkage. Support for the amendment to claim 26 can be found at paragraph [0032] disclosing that the radial shrinkage is measured by the % change in the outer diameter of the working length of an inflated balloon as part of a catheter

system, versus as formed after the present process, and in the Figures, and at paragraphs [0028], [0033] and [0037] disclosing the blow-molding of the balloon (see also paragraph [0034] disclosing that the present process involves cooling the balloon within the mold under pressure, thus supporting the recitation in claim 26 that the percent radial shrinkage is based on the inflated (pressurized) outer diameter of the balloon in the balloon mold at a substantially ambient temperature).

The terminology “radial shrinkage” would thus be understood to refer to the way in which inflating a blow-molded balloon at a given working pressure produces an inflated outer diameter (related to the mold used to blow-mold the balloon) which is greater than the inflated outer diameter that later results when the balloon is similarly inflated after being exposed to the treatments which cause the radial shrinkage and which are part of preparing the balloon as part of a finished catheter system ready for use. The “change” which quantifies the percent radial shrinkage of the balloon would thus be understood to refer to conditions which produce comparable inflated outer diameters (i.e., conditions which, apart from being before and after the balloon is exposed to treatments which cause the radial shrinkage, would have otherwise produced the same inflated outer diameter).

The Examiner rejected the claims based on Wang et al., stating that Wang (example 1 and table 1) discloses a polymeric balloon having a having radial shrinkage less than 6% and a length of about 2 cm.

However, Wang example 1 discloses a balloon having an inflated outer diameter which is equal to the inner diameter of the balloon mold/nominal outside diameters of the

balloons at ambient temperature. Wang et al. explicitly discloses at col. 6, lines 30-36 that a 3.0 mm size mold was used to produce a 3.0 mm balloon. Additionally, although Wang discloses the growth of the balloon as the inflation pressure is increased to pressures above the inflation pressure used to inflate the blow-molded balloon, in contrast, Applicant's claim 26 requires dimensional stability at the inflation pressure used to inflate the blow-molded balloon to its inflated configuration, as discussed above. Therefore, although Wang does disclose non-compliant balloons which have a limited, 2-7%, diameter increase as the balloons are pressurized above e.g., 6 atm, Wang is comparing the inflated outer diameter at the nominal inflation pressure of the balloon to an inflated outer diameter at a different, higher inflation pressure, such that Wang does not disclose or suggest a balloon having a radial shrinkage of less than 10% but greater than 0% as required by Applicant's claim 26.

Moreover, Applicant's claim 26 requires that the balloon (heat set using a heating member applying heat simultaneously along the length of the balloon) has an inflated outer diameter radial shrinkage which is less than that of a balloon heat-set nonuniformly, which would not appear to be the case for an inflated outer diameter change envisioned by the Examiner as being due merely to an increasing inflation pressure while inflating a blow-molded balloon in Wang.

Applicant respectfully requests reconsideration, and issuance of a timely Notice of Allowance.

Respectfully submitted,

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